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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/030,793	01/11/2002	Victor Klimyuk	ICON-002	4086
530 7590 01/25/2007 LERNER, DAVID, LITTENBERG, KRUMHOLZ & MENTLIK 600 SOUTH AVENUE WEST WESTFIELD, NJ 07090			EXAMINER MEHTA, ASHWIN D	
			ART UNIT	PAPER NUMBER
			1638	
SHORTENED STATUTORY PERIOD OF RESPONSE		MAIL DATE	DELIVERY MODE	
3 MONTHS		01/25/2007	PAPER	

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No. 10/030,793	Applicant(s) KLIMYUK ET AL.	
	Examiner Ashwin Mehta	Art Unit 1638	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 31 October 2006.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1,2,5-9,11,12,14-16,18 and 36-41 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1,2,5-9,11,12,14-16,18 and 36-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 January 2002 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
2. The amendment filed October 31, 2006 was entered.
3. The objection to the specification for reciting an incorrect bibliographic citation is withdrawn, in light of its amendment.
4. The rejection of claims 4, 43, and 44 under 35 U.S.C. 112, second paragraph is withdrawn, in light of the claim cancellations.
5. The rejection of claims 4, 19, 43, and 44 under 35 U.S.C. 112, first paragraph is withdrawn, in light of the claim cancellations.

Claim Rejections - 35 USC § 112

6. Claim 12 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

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The claim is broadly drawn towards a method of making a plant artificial chromosome, the method comprising preparing recombinant protoplasts of a first plant species containing an exogenous nucleic acid comprising at least one restriction site, wherein the at least one restriction site comprises at least one recombination site recognized by a site-specific recombinase.

The claim as currently written reads on the nucleotide sequence of a restriction site containing one or more recombination sites recognized by a site-specific recombinase. While the specification discusses the presence of such site-specific recombination sites in the exogenous nucleic acid of a plant protoplast to be irradiated, it does not provide written descriptive support for such sites actually being within restriction enzyme sites, as currently encompassed by the amended claim. The specification does not describe any restriction enzyme recognition sites into which a site-specific recombination site can be inserted, and still be recognized as a substrate for the restriction enzyme. Amended claim 12 recites NEW MATTER that must be removed.

Claim Rejections - 35 USC § 103

7. Claims 1, 2, 5-9, 11, 14-16, 18, and 36-41 remain rejected under 35 U.S.C. 103(a) as being unpatentable over Famelaer et al. (Theor. Appl. Genet., 1990, Vol. 79, pages 513-520) in combination with Blume et al. (Plant Journal, 1997, Vol. 12, pages 731-746) and Adam et al. (Plant J., 1997, Vol. 11, pages 1349-1358), for the reasons of record stated in the previous Office actions. Applicants traverse the rejection in the paper filed October 31, 2006. Applicants' arguments have been fully considered but were not found persuasive.

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Applicants argue that an obviousness rejection cannot be based solely on the fact that the missing step is old in the art, that absent any supporting evidence or reasoning, the determination that motivation to combine exists exclusively on the basis of “common knowledge and common sense” amounts to nothing more than an attempt by the Office to shift the initial burden of establishing a *prima facie* case of obviousness on Applicants, requiring Applicants to disprove obviousness before it is established (response, page 8, 3rd full paragraph and to paragraph bridging pages 9-10). However, previous Office actions did provide motivation to use the method of Famelaer et al. with transgenic lines, in order to introgress a desired trait conferred by the transgene into a desired recipient line. Famelaer et al. teach that monosomic or disomic addition lines have been used in breeding programs as starting breeding material for the introgression of desirable characteristics (page 519). Applicants again argue that Famelaer found that chromosome fragments were not stably inherited, and particularly argue that the ME isozyme was not expressed in any of the hybrids and the ShDh isozyme was almost completely lost as early as the first generation progeny (response, page 10, 1st full paragraph). However, as discussed in previous Office actions, Famelaer et al. do report a normalization of the transmission rate, presence of mini-chromosomes, and obtainment of self-fertile hybrids. It is unclear why Applicants are pointing out the ME and ShDh isozymes, since the instant claims do not require any particular isozymes to be present, or that any particular level of efficiency of the claimed method is required. Further, Applicants’ own working examples in the instant specification show that the plants they obtain may contain only a few chromosomes from the donor parent (page 13 lines 17-24); that the total number and exact type of chromosomes were difficult to establish because small variations in chromosome number may exist in a regenerant,

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or radiation damage of donor chromosomes may result in recipient-like chromosomes, or that interspecific chromosome exchanges may result in reconstructed and deleted recipient chromosomes as well as in the loss of chromosomes (page 14, line 19 to page 15, line 4). It does not appear that Applicants' invention is based on results that increase the efficiency of or improve prior art methods of fusing irradiated plant protoplasts with non-irradiated protoplasts to produce fused protoplasts and plants regenerated therefrom that contain minichromosomes. Applicants also argue, regarding the amendatory claim language, that one of ordinary skilled in the art would not have been motivated to modify Famelaer's method by transforming protoplasts with exogenous nucleic acid comprising at least one restriction site (response, paragraph bridging pages 10-11). However, the practice of using a plant transformation vector comprising a multiple cloning site to insert a transgene of interest into a plant is a long-established practice in the art. The plasmid constructs used in Blume et al. and Adam et al. comprise restriction sites (Blume et al., page 743; Adam et al., pages 1355-1356). Applicants also argue, regarding the amendatory language, that pages 8 and 10-12 of the specification disclose that the recombination sites allow for the further genetic manipulation and movement of the artificial chromosomes after its "selection" (response, paragraph bridging pages 10-11). The cited references do not teach recombination sites recognized by a site-specific recombinase, and therefore the rejection is withdrawn from claim 12. However, the remaining claims do not mention anything about further genetic manipulation and movement of the artificial chromosome. Applicants' arguments are not commensurate with the scope of the claims.

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Summary

8. Pending claims 1, 2, 5-9, 11, 12, 14-16, 18, and 36-41 remain rejected.
9. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

Contact Information


Any inquiry concerning this or earlier communications from the Examiner should be directed to Ashwin Mehta, whose telephone number is 571-272-0803. The Examiner can normally be reached from 8:00 A.M to 5:30 P.M. If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Anne Marie Grunberg, can be reached at 571-272-0975. The fax phone numbers for the organization where this application or proceeding is assigned are 571-273-8300. Patent applicants with problems or questions regarding electronic images that can be viewed in the Patent Application Information Retrieval system (PAIR) can now contact the USPTO's Patent Electronic Business Center (Patent EBC) for assistance. Representatives are available to answer your questions daily from 6 am to midnight (EST). The toll free number is (866) 217-9197. When calling please have your application serial or patent number, the type of document you are having an image problem with, the number of pages and the specific nature of the problem. The Patent Electronic Business Center will notify applicants of the resolution of the problem within 5-7 business days. Applicants can also check PAIR to

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For all other customer support, please call the USPTO Call Center (UCC) at 800-786-9199.

January 17, 2007



Ashwin D. Mehta, Ph.D.
Primary Examiner
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